SEP - 8 2000

K001725

510(k) Summary for Heartstream XL Defibrillator/Monitor

Date Summary Prepared

June 2, 2000

Submitter's Name and Address

Agilent Technologies
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Contact Person

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Device Name

Proprietary Name:	Heartstream XL Defibrillator/Monitor
Common Name:	Defibrillator/Monitor
Classification Names:	Low-Energy Defibrillator, Defibrillator Automatic External, External Transcutaneous Pacemaker (noninvasive), and Monitor Physiological Patient

Predicate Devices

The legally marketed devices to which Agilent Technologies claims equivalence for the Heartstream XL Defibrillator/Monitor are as follows:

- The HP (Agilent Technologies) Heartstream XLT Defibrillator/Monitor,
- The Zoll M Series Biphasic, Hospital Defibrillator,

The design of the Heartstream XL Defibrillator/Monitor is substantially equivalent in safety and performance to the devices listed above.

Device Description

The Heartstream XL Defibrillator/Monitor has two modes of operation: AED and manual. In manual mode, the Heartstream XL is a fully-featured manual defibrillator, designed for use by clinicians trained in Advanced Cardiac Life Support (ACLS) procedures. Manual operation allows users to select energy levels for external defibrillation, deliver synchronized shocks, and perform non-invasive external pacing.

As an AED, the Heartstream XL can be tailored to meet the needs of most BLS users, from basic AED, to an AED with monitoring parameters. In AED mode, voice prompts guide the user to deliver defibrillation shocks when required.
Sp02 and 3 or 5 wire ECG monitoring is also available.

The Heartstream XL defibrillator uses the Heartstream SMART Biphasic waveform for defibrillation, the same proven waveform utilized in the Heartstream XLT Defibrillator/Monitor.

ECG data and events can be stored on a Data Card by the Heartstream XL for later downloading and reporting with the Heartstream CodeRunner data management system.

Intended Use

The Heartstream XL Defibrillator/Monitor is a fully featured, external defibrillator intended for use by qualified medical personnel, trained in either Advanced Cardiac Life Support or Basic Life Support, in a hospital environment.

Comparison of Technology Characteristics

The Heartstream XL Defibrillator/Monitor employs the same technologies as the predicate devices used for comparison. The XL acquires and analyzes ECG signals like the predicates, utilizes the same shock advisory criteria utilized in the Heartstream XLT, and advises the user to deliver a shock when required utilizing voice prompts as in the Heartstream XLT. The Heartstream SMART Biphasic waveform is utilized for defibrillation shocks, as in the Heartstream XLT. Heart rate alarms, noninvasive pacing and pulse oximetry functions are provided, as in the Heartstream XLT. The XL's SpO_2 technology is identical to the Heartstream XLT. The battery type and chemistry are the same as the Heartstream XLT battery.

Nonclinical Tests Used in Determination of Substantial Equivalence

The objective of the testing performed on the Heartstream XL Defibrillator/Monitor was to determine whether any of the device's new or revised functions raise any questions regarding the safety or effectiveness of the device. The philosophy of this approach is that if the Heartstream XL passes equivalent tests done with the previous devices, then it can be concluded that there are no questions with respect to safety or effectiveness of the new Heartstream XL.

For each function on the Heartstream XL that is leveraged from the Heartstream XLT, the testing done for the previous product was repeated in order to demonstrate equivalence, although in some cases, more stringent procedures and/or acceptance criteria were required for the XL. In other cases, the features of the predicate devices are identical to those on the Heartstream XL and did not require repetition.

The nonclinical tests used in determination of substantial equivalence included only bench testing. Bench testing includes hardware, algorithm and software testing.

Conclusion from Testing

Based on the results of the testing described above, it is concluded that the Heartstream XL does not raise any different questions regarding the safety or effectiveness as compared with the predicate devices. It is considered to be substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP - 8 2000

Mr. Richard J. Petersen
Agilent Technologies, Inc.
3000 Minuteman Road
Andover, MA 01810-1099

Re: K001725
Heartstream XL, Model M4735A
Regulatory Class: III (three)
Product Code: 74 MKJ, DRO, LDD, DQA
Dated: August 7, 2000
Received: August 10, 2000

Dear Mr. Petersen:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597, or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K001725

Device Name: Agilent Technologies, Heartstream XL Defibrillator/Monitor

Indications For Use: The Heartstream XL Defibrillator/Monitor is to be used for the termination of ventricular tachycardia and ventricular fibrillation.

This device is for use in the hospital by qualified medical personnel trained in the operation of the device and qualified by training in basic life support, advanced cardiac life support, or defibrillation. It must be used by or on the order of a physician.

The SMART Biphasic waveform utilized in the Heartstream XL Defibrillator/Monitor has previously undergone clinical testing in adults. These trials support the waveform's effectiveness for defibrillation of ventricular tachyarrhythmias at the 150J energy level.

AED Therapy:
To be used in the presence of a suspected cardiac arrest on patients of at least 8 years of age that are unresponsive, not breathing and pulseless.

Manual Defibrillation:
Asynchronous defibrillation is the initial treatment for ventricular fibrillation and ventricular tachycardia in patients who are pulseless and unresponsive. The SMART Biphasic waveform utilized in the Heartstream XL Defibrillator/Monitor incorporates some user selectable lower energy levels that were not used in the clinical trials.

There are currently no clinical studies related to the use of SMART Biphasic waveform in pediatric applications or direct defibrillation of the heart during open chest surgical procedures.

Pacing:
Noninvasive pacing is one method of treating patients with symptomatic bradycardia. It can also be helpful in patients with asystole, if performed early.

SpO_2 Monitoring:
SpO_2 monitoring is indicated for use when it is beneficial to assess a patient's oxygen saturation level.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ or Over-The-Counter Use _____

(Per 21 CFR 801.109)

Division of Cardiovascular & Respiratory Devices
510(k) Number K001725